

## **Understanding the core principles of a ‘modified ketogenic diet’: a UK and Ireland perspective.**

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The Ketogenic Dietitians Research Network (KDRN) is a consortium of ketogenic dietitians who collaborate on research projects to champion dietetic-led research and improve the evidence base for ketogenic dietetics in neuroscience.

**Key words:** Ketogenic; Epilepsy; Modified ketogenic diet.

**Acknowledgements:** Thank you to the members of the Ketogenic Dietitians Research Network (KDRN) for their support and expertise including the participating centres (Addenbrookes Hospital; Alder Hey Children's Hospital; Bristol Royal Hospital for Children; Glasgow Royal Hospital for Children; Great North Children's Hospital; Great Ormond Street Hospital; Leeds Children's Hospital; Leicester Royal Infirmary; Matthew's Friends Clinics; Nottingham University Hospitals; John Radcliffe Hospital, Oxford; Royal Manchester Children's Hospital; Royal Preston Hospital, Sheffield Children's Hospital; Southampton General Hospital; Southmead Hospital; Temple Street Children's University Hospital; The National Hospital for Neurology and Neurosurgery, University College Hospital London; The Walton Centre NHS Foundation Trust).

**Conflicts of interest:** Matthew's Friends Charity, Nutricia Advanced Medical Nutrition and Vitaflo (International) Ltd sponsored meetings for the Ketogenic Dietitians Research Network (KDRN), one of which was used to formulate this project. KJM receives a PhD studentship from Vitaflo (International) Ltd. BL is a full time employee of Vitaflo (International) Ltd. NES is supported by a research grant from Vitaflo (International) Ltd. VJW, SW, EGN and ZRS have no conflicts of interest.

## **Abstract**

**Background:** Many centres across the UK and Ireland anecdotally report using a ‘modified ketogenic diet’ (MKD) as a treatment for refractory epilepsy. Whilst a MKD is within the spectrum of ketogenic diets (KDs), there is little literature reporting upon its definition, use or clinical effectiveness. We aimed to understand the core principles of MKD practice and to assess if and how the MKD differs from other KD protocols.

**Methodology:** An online survey, designed by a consensus group of ketogenic dietitians, was circulated to 39 KD centres across the UK and Ireland. It consisted of 35 questions regarding dietetic practice when providing MKD.

**Results:** Eighteen centres completed the questionnaire: 13 paediatric, 3 adult and 2 combined centres. All dietitians based MKD ‘prescriptions’ on estimated total energy requirements. The average macronutrient profile was 75% fat, 5% carbohydrate with protein *ad libitum*. Carbohydrate and fat targets were implemented through weighed portions (carbohydrate lists n=18; fat lists n=13) and ‘household measures’ (CHO lists n=2; fat lists n=3). 94% (n=17) adjusted macronutrients over time; these decisions were based on ketone levels and seizures in most centres (83%; n=14). Ketogenic nutritional products available on prescription were used by 10 centres (56%) when initiating and by all centres when ‘fine tuning’ the MKD.

**Conclusion:** MKD in the UK and Ireland is a hybrid KD, adopting principles from other established KD protocols and defining new elements unique to the MKD. Further research into the clinical and cost-effectiveness of MKD would be of benefit.

## **Introduction**

Ketogenic diets (KDs) for the dietary management of epilepsy and neurometabolic conditions have undergone a worldwide renaissance and reported increase in use over recent decades (1–3). Clinical and scientific research has confirmed degrees of efficacy (4), revealed possible mechanistic insights (5) and, more recently, indicated their potential as adjunctive treatments for an ever-widening range of other medical conditions (6–8). However, acceptability of KDs and adherence to the requisite, habitual, very low-carbohydrate, very high-fat intake is known to be variable and problematic, particularly for adults (9–11).

Historically, two distinct protocols exist for implementation of KDs – the 1920s ‘classical’ ketogenic diet (CKD) (12,13), and an adaptation of this, from the 1970’s, incorporating medium chain triglycerides (MCT KD) (14). Whilst both are proven effective in reducing seizure frequency (15) and are currently used in clinical practice, they are inherently complex, requiring detailed calculation, education and training, precise weighing and careful food preparation (16).

Alongside the resurgence of interest in KDs, two further, clinically evaluated and efficacious ‘modifications’ of the CKD with well-defined protocols were created in the 2000s - the modified Atkins diet (MAD) (17,18) and the low glycaemic index treatment (LGIT) (19,20). Whilst strict control of carbohydrate and a high fat intake remain vital, in comparison to the two traditional versions of the KD, these regimes are characterised by simpler, more pragmatic accessibility and application by patients, caregivers and health care professionals (21–23).

In recent publications from the United States of America (USA), the MAD and LGIT are placed under an umbrella term of ‘modified ketogenic diets’ when practiced and followed as per protocols (16,24). Centers across the United Kingdom (UK) and Ireland anecdotally report using a ‘modified ketogenic diet’ (MKD) for refractory epilepsy, but their methods for implementation seem to differ from the MAD or LGIT protocols. The approach is also distinct in terms of individualised ‘fine-tuning’ to achieve optimal ketosis, adherence and management of adverse side effects (25). Interpretation of what exactly constitutes this type of MKD is lacking. It is unclear if it is a distinct version of KD with its own unique protocol, and there is insufficient evidence for its comparative efficacy. In addition, in the literature, use of a KD called ‘MAD’ that differs from its primary design is described, as is use of a ‘modified ketogenic diet’ (MKD), a hybrid approach incorporating aspects from all four of

the established KD protocols (11,26–31). The practice of KDs is seemingly evolving and it is important to gain an insight into the MKD as practiced in the UK and Ireland to advance and facilitate dietary interventions in the future.

The aims of this study were i) to understand the core principles of MKD in practice and ii) to assess if and how a MKD differs from other KD protocols.

## **Methods**

A survey was developed by a consensus group of ketogenic dietitians from adult and paediatric centres across the UK and Ireland, who form the Ketogenic Dietitians Research Network (KDRN). The survey comprised of 35 questions. Data collected included service demographics, dietary preparation and education, initiation of the diet (including macronutrient profile, dietary calculations and resources), ‘fine-tuning’, monitoring and dietary discontinuation when relating to the use of a MKD protocol in clinical practice. The survey incorporated background information about different KDs to assist clinicians in providing informed responses.

The survey was circulated to all KD centres across the UK and Ireland (n=39). Data was collected between December 2017 and January 2018 and approved by the audit and research departments of individual centres as required.

## **Results**

### *Demographics*

Eighteen centres across the UK and Ireland completed the questionnaire: 13 paediatric centres, 3 adult centres and 2 combined centres. All centres offered a MKD within their KD service.

### *Dietary preparation and education*

In preparation for commencing a MKD, 89% of centres (n=16) requested a baseline food diary to assess habitual eating habits and as a basis for estimating total energy requirements. Most centres (72%, n=13) also advised patients to make initial dietary modifications before commencing a MKD. These modifications included reducing dietary intake of high sugar foods and overall carbohydrates, over a 4 to 6 week period. Education for patients and families was offered as a combination of group and individual appointments (94%, n=16).

### *Dietary initiation*

A MKD was initiated in an outpatient setting (100%, n=18). All centres (n=18) based the MKD macronutrient calculations on estimated total energy requirements and 65% (n=11) of centres commenced the diet gradually over a period of seven days or less.

With regards to carbohydrate consumption, all centres (n=18) provided a specific carbohydrate target. This was based upon a predetermined weight between 15-30 grams/day in 67% of centres (n=12) and based upon 5% of the estimated total energy requirements in 28% of centres (n=5). One centre calculated carbohydrate to provide between 10-20% of estimated total energy. All centres (n=18) provided a weighed portion list for carbohydrate when educating patients and families, 11% of centres (n=2) also provided a portion list based upon household measures (e.g. tablespoons). All centres advised carbohydrate to be evenly distributed throughout the day.

All centres (n=18) provided a specific target for the consumption of fat. When providing further details (n=16), most centres (75%, n=12) based this fat target on estimated total energy requirements, with fat providing 65-80% of total energy. One centre (6%) based the fat target upon a predetermined weight of 10g fat to 1g of carbohydrate. Three centres (19%) calculated dietary fat targets as a remainder of total energy, after accounting for carbohydrate and protein. Seventy-two percent of centres (n=13) provided a weighed portion list for fat when educating patients and families, 11% (n=2) provided household measurements only and 17% (n=3) centres offered both weighed and household measure lists. The majority of centres (89%, n=16) advised fat intake to be distributed evenly throughout the day and 39% (n=7) provided the patient and family with guidance upon different types of dietary fats (saturated and unsaturated fats).

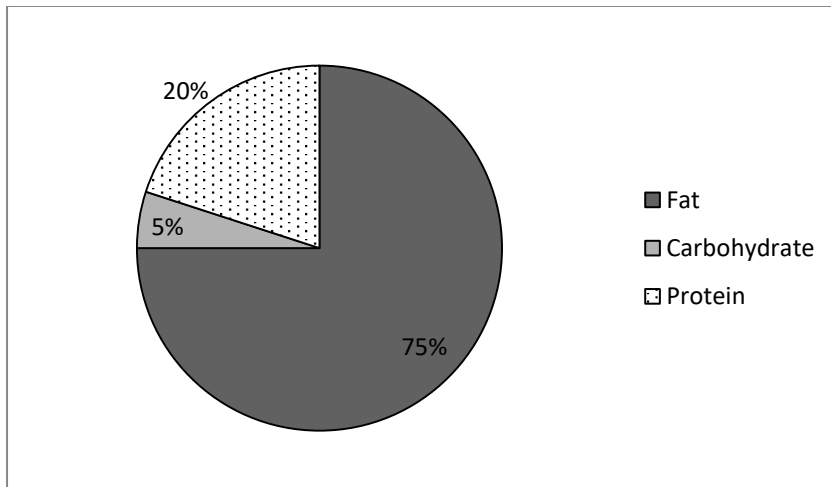
Four centres (22%) provided patients with a protein target. In these cases, protein was calculated to provide 20-25% of estimated total energy requirements. Patients and families were provided with weighed portion lists for protein foods and protein was encouraged to be evenly distributed throughout the day.

When translating these macronutrient calculations into food, 83% of centres (n=15) provided patients and families with recipes, 83% (n=15) offered advice on food labelling and 72% of centres (n=13) provided meal plans.

Ketogenic nutritional products available on prescription were used by 56% of centres (n=10) when initiating a MKD. These products consisted of MCT products in 60% of these centres (n=6) and both MCT and long chain triglyceride (LCT) products in 40% of these centres (n=4). The majority of centres (83%, n=15) prescribed a multivitamin and mineral supplement to all patients.

Figure 1 provides an illustration of the average macronutrient profile of a MKD at initiation.

Figure 1: Average macronutrient profile of a MKD at initiation.



NB: Percentages of estimated total energy requirements. Macronutrient composition varies by centre (chart represents average proportions).

Carbohydrate target 15-30g/day (n=15) or 5% estimated total energy requirements (n=3). Dietary protein target defined in limited number of centres.



### *'Fine tuning'*

Macronutrients were 'fine-tuned' over time in 94% of centres (n=17). Of these centres (n=17), 83% (n=14) based dietary changes on ketone levels and seizure frequency. Seventeen percent of centres (n=3) based changes on ketone levels alone.

Whilst the majority of centres did not define protein portions initially, 71% of centres (n=12) did introduce protein guidance during the 'fine-tuning' phase, as a possible strategy to enhance ketosis, when required.

All centres (n=18) considered the use of ketogenic nutritional products available on prescription during the 'fine-tuning' phase, with 83% of centres (n=15) using a combination of MCT and LCT products, 6% (n=1) using MCT products only and 11% (n=2) using LCT products only.

### *Monitoring*

When monitoring ketone levels, 56% of centres (n=10) used blood ketone monitoring, 5% (n=1) used urinary ketones and 39% (n=7) used a combination of urinary and blood ketone monitoring. There was no overall consensus for the scheduling of follow up appointments, with clinical practice varying between daily and weekly telephone contact, to three monthly face-to-face clinic appointments.

### *Dietary discontinuation*

Information regarding dietary discontinuation was provided by 16 centres. This was undertaken over a period of seven days or more in most centres (88%, n=14) and over a period of less than seven days in 12% of centres (n=2).

Table 1 provides a comparison of a MKD protocol to other established KDs.

**Table 1: A summary comparing MKD to other KDs**

<b>Dietary element</b>	<b>LGIT</b>	<b>MAD</b>	<b>MKD</b>	<b>MCT KD</b>	<b>CKD (e.g. 4:1)</b>
<b>Carbohydrate</b> (excluding fibre)	10% ETER GI < 50	10-20g/d	15-30g/d or 5% ETER	15-18% ETER	4% ETER
<b>Fat</b>	60% ETER	Ad lib (LCT)	60-80% ETER (LCT/ MCT)	72-75% ETER (30-60% MCT)	90% ETER (LCT)
<b>Protein</b>	30% ETER	Ad lib	Ab lib	10% ETER	6% ETER
<b>Food measurements</b>	Weighed/ household measures	Visual	Weighed/ household measures	Weighed	Weighed
<b>Ketone testing</b>	Urinary	Urinary	Urinary and blood	Blood	Blood
<b>Prescribed ketogenic nutritional products</b>	No	Initiation only(LCT)	Yes (LCT/MCT)	Yes (MCT)	Yes (LCT)

Abbreviations; CKD = classical ketogenic diet; GI = glycaemic index; LCT = long chain triglyceride; LGIT = low glycaemic index

treatment; MAD = modified Atkins diet; MCT KD = medium chain triglyceride ketogenic diet; MKD = modified ketogenic diet; ETER = estimated total energy requirement; ratio 4:1 = 4g of fat to 1g of carbohydrate and protein combined. LGIT, MAD, MCT KD and CKD as defined in Neal et al. (2012), Kossoff et al. (2011), Kossoff et al. (2018) and McDonald et al. (2018) (16,32–34).

## Discussion

Whilst the term 'MKD' has recently been used by US authors to describe MAD and LGIT protocols (16,24), in the UK and Ireland, 'MKD' has been coined as an umbrella term for modern day KDs that diverge beyond traditional KD protocols such as CKD (12,13), MCT KD (14), MAD (17,18) and LGIT (19,20). However, prior to this study, little was known about the clinical implementation of MKD in the UK and Ireland or the differences between MKD and these other KDs. The results of this study provide a novel insight and illustrate MKD to be a hybrid of these four KDs protocols and a distinctly different use of the term 'MKD' used to describe rigid MAD and LGIT protocols from the USA.

Results of this survey indicate MKD to be used widely across the UK and Ireland, in both adult and paediatric populations. Dietary preparation through a reduction in carbohydrate and high sugar foods is key for implementation, complementing other KD protocols (32). Interestingly, patient education was offered solely in an outpatient setting and the majority of centres delivered this education via group and individual appointments, with group education offering potential cost savings for healthcare services (11).

In relation to calculating MKD nutritional requirements, the practice adopted by CKD and MCT KD protocols was utilised, with an estimation of total energy requirements being the basis for establishing macronutrient requirements. Carbohydrate requirements varied between 15-30 grams/day, seen previously in MAD protocols (35–37) or through a novel approach of 5% of estimated total energy requirements, currently unique to the MKD described in this study. For fat, requirements and education styles followed the stricter CKD (12,13) and MCT KD protocols (14), with fat being weighed or measured to provide 65-80% of estimated total energy requirements, rather than offered *ad lib* as in MAD (17,18). Ketogenic nutritional products available on prescription were also utilised on dietary initiation and 'fine-tuning', combining MCT and LCT prescription products. This is a novel approach taken by MKD, as CKD utilises LCT products, MCT KD utilises MCT products and, in recent years, the MAD includes LCT products but during initiation only (34).

Over time, these macronutrients were increased or decreased based upon seizure control and/or ketone levels by all centres, this is known as a period of 'fine-tuning' and usually observed in CKD and MCT KD protocols. Monitoring of ketone levels was undertaken through blood and/or urinary ketone testing in the majority of centres, a hybrid of the approaches taken by the other KDs.

Unfortunately, no consensus could be derived regarding appointment duration or follow up requirements for the MKD, due to the variability in service designs across the UK and Ireland – an area for further research.

Whilst MKD was within the spectrum of KDs, little is known about the clinical effectiveness, cost-effectiveness or side effects of this type of KD in patients with epilepsy, nor how it compares with other KD types. Further research in a clinical trial setting is warranted. For KD clinicians, MKD offers the dietary ‘control’ offered by CKD, the flexibility of MAD and the supplemental benefits of MCT KD. However, little is known about patient or family experience of MKD and qualitative research in this area would be beneficial.

This study has several limitations. The survey was not validated and could be subject to reporter bias. Researcher imposition should also be considered, as the survey was designed by a consensus group of dietitians from KDRN, and their views may not reflect issues considered to be important in the wider KD dietetic community who practice MKD. To our knowledge, 39 centres practice KDs within the UK and Ireland, 18 of which completed this survey; therefore the views of the other centres remain unknown. As the survey was completed in the UK and Ireland, it may be difficult to extrapolate the results to other countries around the world that practice MKD. Therefore, further research into MKD practice worldwide would be of benefit to assess how it compares and contrasts to this UK and Ireland perspective.

In conclusion, MKD in the UK and Ireland is a hybrid KD, adopting principles from other established KD protocols and defining new elements unique to the MKD, suggesting MKD to be a KD in its own right. Further research into the clinical and cost-effectiveness of MKD would be of benefit.

### **Transparency Declaration**

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained.

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